EXHIBIT 16

Rebuttal Expert Report of Dr. Howard Ory

I. Introduction

A. Educational Background and Professional Experience

My name is Howard William Ory, MD., M.Sc. I received my medical degree from Tufts University in 1969 and a master's degree in epidemiology from Harvard University, School of Public Health, in 1974. I am a fellow of the American College of Preventive Medicine. I am a member of the American Epidemiologic Society as well as a member of the Society of Epidemiological Research. I am licensed to practice medicine in Georgia and I am board certified in preventive medicine.

I spent approximately twenty-three years of my professional career working for the United States Centers for Disease Control ("CDC"). During my tenure at the CDC, I served in the following capacities: Deputy Director for Research, Epidemiology Program Office; Deputy Director, Division of Reproductive Health; Chief of the Epidemiologic Studies Branch, Family Planning Division; and Director of the Information Resources Management Office. In these positions, my responsibilities included not only teaching epidemiologic methods to epidemiologists in training but also teaching continuing education courses to the CDC's senior epidemiologists.

After my retirement from the CDC in 1994, I was employed by the Prudential Center for Health Care Research. I served as Vice President and Senior Scientist until my retirement in1996, at which time I became a private consultant.

I have served as a member of, and consultant to, committees of the World Health Organization, the United States Food and Drug Administration, and the CDC. I have written extensively on epidemiological issues and my work has been published widely in peer reviewed, professional literature.

I have extensive experience in the areas of conducting epidemiologic studies, teaching others how to perform epidemiologic analyses, as well as disease surveillance and disease estimation methodology. I have authored or co-authored over 100 articles in the medical literature. Many of these articles pertain to case-control and cohort epidemiologic studies, chronic diseases such as cancer, or issues of epidemiologic study design. Among these more recent reports include a long term mortality follow-up from the cancer and steroid hormone study. I prepared the epidemiologic study design for and carried out the Cancer and Steroid Hormone Study conducted by the CDC and sponsored by the National Institutes of Health (NIH). This study involved nearly 10,000 subjects. It took 3 years to develop the protocol, 3 years to interview the subjects and, while its main results were published in the late 1980s, data from it are still being analyzed and form the basis of scientific reports some 20 years later.

B. Tasks I Have Been Asked to Perform

I have been asked to review Dr. Alan Whitehouse's expert report dated December 29, 2008 as well as his March 12, 2009 supplemental report and comment on the scientific validity of the reports. In particular I've been asked to comment on the CARD mortality data reported by Dr. Whitehouse in that expert report and the 2004 Whitehouse published paper "Asbestos-related Pleural Disease Due to Tremolite Associated with Progressive Loss of Lung Function: Serial Observations in 123 Miners, Family Members, and Residents of Libby, Montana."

C. Materials I have reviewed

I reviewed Dr. Whitehouse's 2004 and 2008 published reports on pleural disease and mesothelioma in Libby, Montana. I have reviewed Dr. Whitehouse's expert report dated 12/29/2008. Further, I have reviewed Dr. Whitehouse's recent deposition dated March 19, 2009 as well as his March 4, 2009 testimony in the *U.S. v. W.R. Grace*. I have also reviewed Dr. Arthur Frank's December 23, 2008 expert report, Dr. Whitehouse General affidavit to Libby Opposition (June 2005), Dr. Whitehouse Questionnaire Affidavit to Libby Opposition (June 2005), and Dr. Whitehouse Expert Disclosure for *U.S. v. W.R. Grace* (September 2005). In addition, I reviewed the several reports and publications by the ATSDR about their examinations of the people in Libby Montana, including the published Peipins report, November 2003; Mortality in Libby Montana, 1979-1998, both the first (12/12/2000) and updated reports(8/8/2002); Preliminary Findings of Medical Testing of Individuals Potentially Exposed to Asbestiform Minerals Associated with Vermiculite in Libby Montana: An Interim Report, February 22, 2001 as well as the final report 8/23/2001; and A Review of Asbestos Related Abnormalities Among a Group of Patients from Libby Montana: A Pilot Study of Environmental Cases, Final Report, August 2002. I also rely on the published documents cited in this report.

II. Epidemiologic methods

If a scientist wishes to study the effects of an exposure such as asbestos in a group of people, he would conduct a controlled epidemiologic study. One type of controlled epidemiologic study is a cohort study. A cohort study consists of a group of people with the exposure of interest (in this instance Libby vermiculite) and a group of control people who are as similar as possible to the people with exposure to Libby vermiculite, except that the control people have not been exposed to

Libby vermiculite (the unexposed). The two groups of people are followed over time. The rates of occurrence of the disease (or diseases) of interest are compared between the exposed and unexposed people. Unless the rate of occurrence of the disease is statistically significantly higher in the people with exposure to Libby vermiculite compared to people without such exposure, no excess risk of the disease exists in the group with the purported exposure, and no scientist or medical doctor can validly state that Libby vermiculite causes the disease in question.

One of the early and classic examples of a cohort study is the study performed by Doll and Hill looking and lung cancer incidence and mortality in British doctors that was first published in 1950. In that study, the authors attempted to enroll all British physicians into a study that began by having them fill out a questionnaire about their smoking habits as well as other personal characteristics. Based on that information, two cohorts were formed: those who never smoked (the unexposed cohort) and those who smoked more than 100 cigarettes in their lifetime (the exposed cohort). Those who smoked were further subdivided by the amount they smoked and the length of time they had smoked. Thus the exposure in these cohorts, the first half of a valid scientific study, was characterized at baseline in a systematic and scientifically valid way. The other half of a valid scientific study, the outcome event, was also systematically measured. The physicians were followed for the rest of their lives with periodic questionnaires concerning their health and by matching their identifying information against death certificates. Thus, the authors were able to compute incidence rates of lung cancer (and other diseases) in those exposed and not exposed to cigarette smoking.

The primary goal of such a controlled cohort study is to compare the ratio of the incidence rates in the exposed and unexposed and in so doing compute the relative risk of lung cancer and other diseases by smoking status. The keys to making this possible are:

1. the cohorts must be comparable (compare-able) to one another, that is, the 2 groups are similar except that one group is exposed to the exposure of interest; and

2. the information about both cohorts has to be collected in a comparable manner, that is, the information about the exposure and the outcome was collected in a way that is well-defined by a protocol, systematic, as free from bias as possible and as complete as possible.

In the Doll and Hill cohort study, the smokers and non-smokers were comparable to one another and the information about lung cancer was collected in a comparable manner in both groups. Thus, it was valid to compare the rates of lung cancer in the two groups and compute relative risks from the ratio of the incidence rates. Furthermore within the group who smoked cigarettes, the authors have valid information about how much and how long they smoked, so the authors were able to compare the different rates of lung cancer by number of cigarettes smoked (dose) and number of years smoked (duration).

I have just described how a study is constructed in an internally valid way, where the two cohorts are comparable and selected in a defined fashion. It is also important that the cohorts be externally valid, that we understand in what ways they are representative of the larger population from which they are drawn. In this case, the investigators studied all male physicians under the implicit assumption that they represent men in general, that men in general are not biologically different from male physicians. Another way the study results can be representative of the population at large

is by getting the information specifically by age, dose, and duration and apply those specific risks in an age, dose and duration specific manner to the population at large.

A variation on the cohort approach that is often done in occupational or environmental exposure settings when it is not possible to identify a true control group, is to use an outside standard of disease incidence rates or death rates as a stand-in for a control group. The ATSDR uses this approach to compute standardized mortality ratios (SMR) using either United States mortality or Montana mortality as the stand-in control group. The SMR approach is described in detail in the December 12, 2000 ATSDR report on mortality from asbestosis in Libby, Montana (page 8). Briefly, the SMR approach consists of taking mortality rates from a reference population, men living in Montana, for example, and multiplying these rates by the number of men living in Libby. In this way, an expected number of deaths for any given disease, asbestosis for example, is generated for men living in Libby. The observed number of deaths from asbestosis is divided by the expected number to yield a mortality ratio that essentially compares the number of deaths from asbestosis in Libby to the number of deaths from asbestosis in Montana. Ninety-five percent confidence intervals are also calculated to deal with the issue of statistical significance of this mortality ratio. In actual practice, an expected number of deaths is computed for each five-year age group and added together to compute a total expected standardized for age. When that age standardized expected value is compared to the observed value, the result is a standardized mortality ratio or SMR.

Like the cohort approach, in order for the SMR approach to be valid, the number of deaths occurring the Libby area has to be ascertained under a well-defined protocol in a systematic fashion, as free from bias as possible and as complete as possible.

Yet another variation on the cohort approach, though producing information that is more problematic to interpret, is to compute a proportional mortality ratio (PMR). This approach is used when numbers of deaths are available for the population of interest, but information on the numbers of people in the underlying population from which the deaths came is not available. For example, if all we knew were the numbers of people who died in Libby and did not know the number of people living in Libby, we would have to use a proportional mortality analysis. In this approach, the percentage distribution of cause of death from an outside standard such as the United States or the state of Montana would be compared to the distribution of deaths for the city of Libby, for example, to generate a proportional mortality ratio (PMR). An example will demonstrate why the PMR is inferior to the SMR. Suppose for some reason in the rest of Montana, an unusually large number of people died from heart disease. This would cause the proportion dying from some other disease of interest, lung cancer, for example, to be unrealistically low because the percentage distribution of deaths in Montana has to add to 100%. In other words, if one cause of death is disproportionately high, all other causes of death will be disproportionately low. So when, for example, the PMR for lung cancer in Libby is computed from the Montana distribution of causes of death, the Libby PMR for lung cancer would be elevated, not because it is truly elevated, but because the proportion of lung cancer in the comparison group was unrealistically low.

Even though the PMR approach is more problematic to interpret than the SMR or cohort approach, the same basic rules apply. In order to have any chance of the PMR being a valid measure of risk, the group of deaths being studied must be collected in a way that is well-defined by a protocol, systematic, as free from bias as possible, and as complete as possible.

III. CARD mortality data reported by Dr. Whitehouse into December 29, 2008 expert report

A. Selection of Subjects in Dr. Whitehouse's data compared to a valid scientific approach to assembling a cohort.

Dr. Whitehouse describes the data he reports on as all patients seen either at CARD or by him in Spokane with asbestos-related disease diagnosis and chest films (paragraph 31, 2008 expert report). In fact, this is a haphazard collection of people who he has seen, who have asbestos-related disease diagnosis chest films and who have died. He does not tell us if everyone he has seen meet those criteria. He begins with 227 potential subjects; 41 were excluded for not meeting the study criteria, leaving 186 in his mortality data. Data was gathered from patient charts and available death certificates including those available through local law firms. This is not an epidemiologically valid approach. In particular, there appears to be no protocol, there is no defined selection process that explains how the 227 individuals are drawn from the larger population of people living in Libby, and Dr. Whitehouse rarely performs statistical tests on this data. In contrast to the ATSDR reports and the mortality study of W.R. Grace employees, Dr. Whitehouse makes no attempt to validly define exposures to Libby vermiculite. Without having followed even rudimentary epidemiological methods, his observations cannot be considered to be scientifically valid.

First, it should be noted that the number of subjects presented in paragraph 31, p 186, Whitehouse 2008 expert report, is inconsistent with data presented in paragraph 35 where Dr. Whitehouse states that "the CARD clinic has diagnosed over 1800 patients with asbestos-related disease..." Dr. Whitehouse includes in his report data on only about one out of every 10 people diagnosed by the CARD clinic with asbestos-related disease. Further he does not describe the

criteria by which the 1800 are selected or reduced to 186 other than what is noted above. In particular, he does not tell us whether it is everyone who has died. A scientist would describe this as a haphazard sampling procedure as opposed to a systematic or random sampling procedure.

One need only compare the CARD mortality data to the various published and unpublished mortality studies among the Libby/Lincoln County residents performed by the ATSDR to highlight what is lacking in the CARD data. The CARD data is a haphazard collection of subjects whose sampling method is not defined or systematic. If it were an epidemiologic study, it would begin with a description of a population and then a well-defined and systematic set of criteria would be developed to select deaths. The method by which patients show up in one doctor's practice is subject to the vagaries of how the patients get referred to the practice. For example, it is possible that people in Libby and Spokane know that Dr. Whitehouse is interested in pleural disease. As such, he may be referred a disproportionately high number of people with pleural disease relative to the distribution of people with pleural disease in Libby. Furthermore, he notes that some of his patients come from a law practice that seems to have an interest in people with pleural disease. Given such a haphazard selection process, it is virtually certain that the 186 people that Dr. Whitehouse reports on are not representative of the Libby population in general. In fact, because of the haphazard and undefined selection process, data on these 186 people cannot be extrapolated to any other population. This would be true for any 186 people selected in such an unscientific fashion. Furthermore, this is true for Dr. Whitehouse or anyone else, including Dr. Arthur Frank, attempting to make statements based on the CARD mortality data.

B. Community exposure claims by Dr. Whitehouse

In subparagraph one of the aforementioned paragraph 31, Dr. Whitehouse notes that 34% of those who died of nonmalignant disease were mine workers while 66% were community members and family members of mine workers. Even if those percentages were correct, as we have seen in the above paragraph, they would not be representative of the Libby population in general. However, in August 2002, the ATSDR reported a review of environmental cases. The ATSDR set out to evaluate 27 potential environmental cases of asbestos-related lung disease. Among the 22 who agreed to participate, ATSDR confirmed only eight as having no occupationally related asbestos exposure. That is, by ATSDR's definition, only eight were potentially environmentally exposed. Of these eight, ATSDR confirmed seven as having x-ray evidence consistent with asbestos-related lung disease. In other words, ATSDR only confirmed approximately 1/3 of the cases that Dr. Whitehouse describes as being solely environmentally exposed cases as having no occupational exposure to asbestos. Clearly, far fewer than the 66% that Dr. Whitehouse reports in subparagraph one were exposed to asbestos solely through environmental exposure.

In addition, the August 23, 2001 ATSDR report concerning the medical testing of individuals concludes on page 26 that "the odds of finding a pleural abnormality was almost eight times greater for former W.R.G. workers when compared to non-workers of the same age." From this, I conclude that the W.R.G. worker exposure and community exposure are of completely different orders of magnitude.

It follows directly from the above ATSDR results that Dr. Whitehouse's comments in subparagraph two are also incorrect. The ATSDR report demonstrates that Dr. Whitehouse does

not know with scientific certainty which subjects in his data are solely environmentally exposed. Therefore, his claim in that subparagraph that the death rate from asbestos disease is not greatly different between mine workers and community members is not based on scientifically valid data. The same would be true for anyone else attempting to use the CARD mortality data to make such a claim.

In addition to the above deficiencies, Dr. Whitehouse pays little attention to the concept of statistical significance. On page 16 of his expert report, where he discusses the CARD mortality data, he notes that "the death rate from asbestos disease was not greatly different as between mineworkers (72%-39/54) who generally had heavy exposures, and community members (54%-58/108), who had light exposures." If Dr. Whitehouse had done a statistical test on this data, he would have noted that the mineworkers had a significantly higher proportion of death from asbestos disease than the community members. His lack of statistical testing further undermines any scientist's ability to draw valid inferences from his report

C. Age at death

Dr. Whitehouse reports in subparagraph nine of paragraph 31 of his 2008 expert report that the mean age at death in the CARD mortality cohort was 76.3. In paragraph 32 of his 2008 report, he presents a table comparing CARD mortality data to data from the insulator cohort initiated by Selikoff and updated in 1997 by Markowitz (page 22). In that table, the average age at death in the CARD mortality cohort is presented as 76.0 years. Putting aside the inconsistency in his numbers concerning the life expectancy of people in the CARD mortality data, Dr. Whitehouse compares the age at death for patients in the CARD mortality data with the age at death in the insulator cohort, which is 65.9 years. I calculate, that according to US vital data, in the year

2005, the average at death for white men over 20, that is, those old enough to be in the workforce, was 71.3 years (derived from NCHS worktable 310 found at http://www.cdc.gov/nchs/data/dvs/mortfinal2005_worktable_310.pdf, last accessed March 28, 2009). Since we do not know what the appropriate comparison group is for men in the CARD data, I also calculate that, on average, the age at death for white US males 55 and older is 76.8 years. The age of death of the subjects in the CARD mortality data, does not appear to be unusual.

Several scientific conclusions are immediately apparent from this data. The average age at death of subjects in the CARD mortality data is certainly no worse than that of white US men of working age. Secondly, the asbestos exposure that the insulator cohort had was unequivocally far more lethal than that experienced by the CARD mortality cohort subjects. That is, the insulators died more than 10 years younger on average than did subjects in the CARD mortality data.

That insulators died on average more than 10 years younger than those in the CARD mortality data is not surprising. Dr. Whitehouse himself notes on paragraph 32, page 19 of his expert report that "the experience of the cohort of asbestos insulation workers provide the context for comparison of Libby mortality from asbestos-related disease. The asbestos insulators had extremely heavy exposures to asbestos dust, often working in clouds of dust. The Libby patients, on the other hand, are mostly community members who had relatively light exposure to asbestos from casual exposure, such as breathing the air in the Libby area." Given Dr. Whitehouse's own description of the differences in exposure between the insulators and residents of Libby, it is not hard to understand why the insulators died on average 10 years younger than those in the CARD